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antibody and further modified by amino acid substitutions

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antibody and further modified by amino acid substitutions

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antibody and further modified by amino acid substitutions

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Phe Gln Gly Ser Trp Tyr Pro Phe Thr
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(51) International Patent Classification:
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(71) Applicant *(for all designated States except US)*: **MEDIMMUNE, INC.** [US/US]; One Medimmune Way, Gaithersburg, MD 20878 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **WEI, Ziping** [US/US]; 11102 Welland Street, North Potomac, MD 21136 (US). **TOUS, Guillermo, I.** [US/US]; 146 Barnsfield Court, Gaithersburg, MD 20878 (US). **SCHENERMAN, Mark** [US/US]; 1 Cornfield Court, Reisterstown, MD 21136 (US). **ALLAN, Christian, B.** [US/US]; 4401 Gregg Road, Brookeville, MD 20833 (US).

(74) Agents: **INSOGNA, Anthony, M.** et al.; JONES DAY, 222 East 41st Street, New York, NY 10017-6702 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

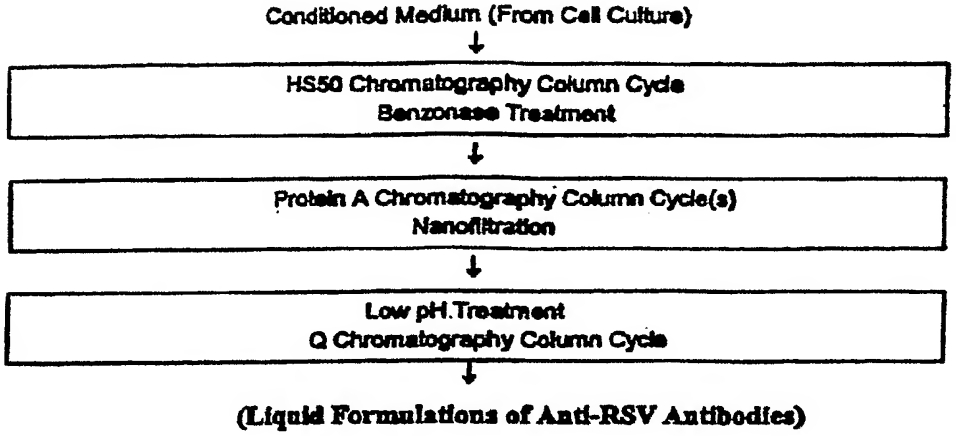
— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
19 July 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ANTIBODY FORMULATIONS HAVING OPTIMIZED AGGREGATION AND FRAGMENTATION PROFILES



(57) Abstract: The present invention provides methods of optimizing the production and purification of antibody formulations that immunospecifically bind to antigens of interest and are suitable for parenteral administration to a subject, which formulations exhibit increased stability due to reduced degradation and aggregation of the antibody component on long term storage. Such methods provide formulations that offer multiple advantages over formulations produced by non-optimized methods including less stringent or more readily available transportation/storage conditions, and less frequent dosing or smaller dosage amounts in the therapeutic, prophylactic and diagnostic use of such formulations. The invention further provides methods of utilizing the formulations of the present invention.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/024717

A. CLASSIFICATION OF SUBJECT MATTER
INV. C07K16/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
C07K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, BIOSIS, WPI Data, Sequence Search, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02/43660 A2 (MEDIUMMUNE INC [US]) 6 June 2002 (2002-06-06) the whole document _____	1-81
Y	DATABASE FDA [Online] Food and Drug Administration; 24 October 2003 (2003-10-24), "Synagis (Palivizumab)" XP002418333 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/LABEL/2004/103770_S5059_LBL.PDF the whole document _____ -/--	1-52, 62-81

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 April 2007	01/06/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lechner, Oskar

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DATABASE FDA [Online] Food and Drug Administration; 2003, "Raptiva (Efalizumab)" XP002418334 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/APPLETTER/2003 /125075-OLTR.PDF abstract	1-52, 62-81
Y	DATABASE FDA [Online] Food and drug administration; 1998, "HERCEPTIN (Trastuzumab)" XP002418335 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/LABEL/1998/TRA SGEN092598LB.PDF the whole document	1-52, 62-81
Y	DATABASE FDA [Online] Food and Drug Administration; June 2003 (2003-06), "Xolair (Omalizumab)" XP002418336 retrieved from HTTP://WWW.FDA.GOV/CDER/FOI/LABEL/2003/OMA LGEN062003LB.PDF the whole document	1-52, 62-81
Y	CHIRINO A J ET AL: "Characterizing biological products and assessing comparability following manufacturing changes" NATURE BIOTECHNOLOGY, NATURE PUBLISHING GROUP, NEW YORK, NY, US, vol. 22, no. 11, 4 November 2004 (2004-11-04), pages 1383-1391, XP002409409 ISSN: 1087-0156 the whole document	53-61
Y	ZIPING WEI (MEDIMMUNE; 24.07.05 2:15): "Explore the analytics of aggregation - overview of techniques for measuring protein aggregation." BARNETT INTERNATIONAL'S ASSESSING THE IMPACT OF PROTEIN AGGREGATION. CONSEQUENCES OF AGGREGATION ON DRUG DEVELOPMENT, IMMUNOLOGY, QUALITY CONTROL, AND DISEASE GENESIS. (23-24 JUNE 2005), [Online] XP002418279 Brussels Marriott. Brussels, Belgium. Retrieved from the Internet: URL:http://www.barnettinternational.com/RS C_PDFUploads//BI2020WEB.pdf> abstract	53-61

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ZIPING WEI (MEDIMMUNE; 30.07.04 09:30): "Application of LC-MS to Characterize Protein Oxidation, Deamidation, Fragmentation and Aggregation." THE PREMIER CONFERENCE ON THE IDENTIFICATION AND VALIDATION OF STABILITY-INDICATING AND FORCED DEGRADATION ASSAYS FOR PROTEINS. ANALYTICAL AND FORMULATION CONSIDERATIONS., [Online] 28 July 2004 (2004-07-28), - 30 July 2004 (2004-07-30) XP002418247 The Sir Francies Drake; San Francisco, CA. Retrieved from the Internet: URL:http://www.biologicsconsulting.com/IIR_Stab_SF_July_2004.pdf> abstract	53-61
Y	SCHUCK-P & BRASWELL-EH: "Measuring protein-protein intreactions by equilibrium sedimentation" CURRENT PROTOCOLS IN IMMUNOLOGY, no. S40, 2000, page 18.8.1-18.8.22, XP002418234 the whole document	53-61
A	EP 1 314 437 A (CHUGAI PHARMACEUTICAL CO LTD [JP]) 28 May 2003 (2003-05-28) the whole document	1-81
A	WO 2004/001007 A2 (IDEC PHARMA CORP [US]; YANG TZUNG-HORNG [US]; BACICA MICHAEL J [US]; L) 31 December 2003 (2003-12-31) the whole document	1-81
A	CHEN BEI ET AL: "Influence of histidine on the stability and physical properties of a fully human antibody in aqueous and solid forms." PHARMACEUTICAL RESEARCH (DORDRECHT), vol. 20, no. 12, December 2003 (2003-12), pages 1952-1960, XP002417746 ISSN: 0724-8741 abstract	1-81
A	WANG WEI: "Instability, stabilization, and formulation of liquid protein pharmaceuticals" INTERNATIONAL JOURNAL OF PHARMACEUTICS, AMSTERDAM, NL, vol. 185, no. 2, 20 August 1999 (1999-08-20), pages 129-188, XP002323952 ISSN: 0378-5173 the whole document	1-81

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10

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	MAHLER H-C ET AL: "Induction and analysis of aggregates in a liquid IgG1-antibody formulation" EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 59, no. 3, April 2005 (2005-04), pages 407-417, XP004780138 ISSN: 0939-6411 abstract	1-81
A	AHRER K ET AL: "Detection of aggregate formation during production of human immunoglobulin G by means of light scattering" JOURNAL OF CHROMATOGRAPHY, ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, NL, vol. 1043, no. 1, 16 July 2004 (2004-07-16), pages 41-46, XP004518349 ISSN: 0021-9673 the whole document	1-81
A	HARRIS R J ET AL: "Commercial manufacturing scale formulation and analytical characterization of therapeutic recombinant antibodies" DRUG DEVELOPMENT RESEARCH, NEW YORK, NY, US, vol. 61, no. 3, March 2004 (2004-03), pages 137-154, XP002324970 ISSN: 0272-4391 the whole document	1-81
A	VIDANOVIC D ET AL: "Effects of nonionic surfactants on the physical stability of immunoglobulin G in aqueous solution during mechanical agitation" PHARMAZIE, DIE, GOVI VERLAG, ESCHBORN, DE, vol. 58, no. 6, June 2003 (2003-06), pages 399-404, XP001247319 ISSN: 0031-7144 abstract	1-81
A	GONZALEZ M ET AL: "THERMAL STABILITY OF HUMAN IMMUNOGLOBULINS WITH SORBITOL" VOX SANGUINIS, S. KARGER AG, BASEL, CH, vol. 68, no. 1, 1995, pages 1-4, XP009070191 ISSN: 0042-9007	1-81

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/024717

C(Continuation). *DOCUMENTS CONSIDERED TO BE RELEVANT*

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	BACK J F ET AL: "INCREASED THERMAL STABILITY OF PROTEINS IN THE PRESENCE OF SUGARS AND POLYOLS" BIOCHEMISTRY, AMERICAN CHEMICAL SOCIETY. EASTON, PA, US, vol. 18, no. 23, 1979, pages 5191-5196, XP002261095 ISSN: 0006-2960 abstract	1-81
A	WO 91/16074 A (MEDIMMUNE INC [US]; JACKSON H M FOUND MILITARY MED [US]) 31 October 1991 (1991-10-31) the whole document	1-81

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/024717

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 51, 52, 78-81 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/024717

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 0243660	A2	06-06-2002	AU	1994402 A	11-06-2002
			CA	2430039 A1	06-06-2002
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			JP	2004534513 T	18-11-2004
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			EP	1551875 A2	13-07-2005
			JP	2005530845 T	13-10-2005
WO 9116074	A	31-10-1991	EP	0530216 A1	10-03-1993

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(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/693,603 23 June 2005 (23.06.2005) US
60/699,614 15 July 2005 (15.07.2005) US

(71) Applicant *(for all designated States except US)*: **MEDIMMUNE, INC.** [US/US]; One MedImmune Way, Gaithersburg, MD 20878 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **WEI, Ziping** [US/US]; 11102 Welland Street, North Potomac, MD 21136 (US). **TOUS, Guillermo, I.** [US/US]; 146 Barnsfield Court, Gaithersburg, MD 20878 (US). **SCHENERMAN, Mark** [US/US]; 1 Cornfield Court, Reisterstown, MD 21136 (US). **ALLAN, Christian, B.** [US/US]; 4401 Gregg Road, Brookeville, MD 20833 (US).

(74) Agent: **MARTINEAU, Janet**; MEDIMMUNE, INC., One Medimmune Way, Gaithersburg, Maryland 20878 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

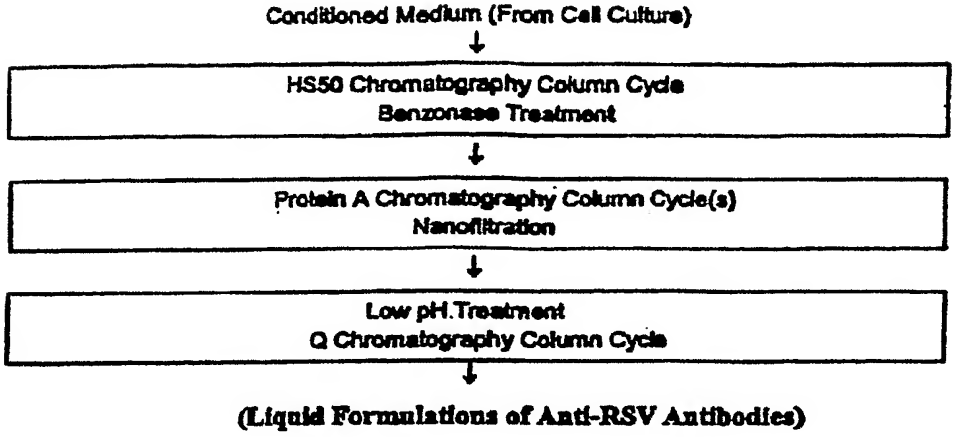
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *with sequence listing part of description published separately in electronic form and available upon request from the International Bureau*

(88) Date of publication of the international search report:
19 July 2007

[Continued on next page]

(54) Title: ANTIBODY FORMULATIONS HAVING OPTIMIZED AGGREGATION AND FRAGMENTATION PROFILES



(57) Abstract: The present invention provides methods of optimizing the production and purification of antibody formulations that immunospecifically bind to antigens of interest and are suitable for parenteral administration to a subject, which formulations exhibit increased stability due to reduced degradation and aggregation of the antibody component on long term storage. Such methods provide formulations that offer multiple advantages over formulations produced by non-optimized methods including less stringent or more readily available transportation/storage conditions, and less frequent dosing or smaller dosage amounts in the therapeutic, prophylactic and diagnostic use of such formulations. The invention further provides methods of utilizing the formulations of the present invention.

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(48) Date of publication of this corrected version:
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(15) Information about Correction:
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